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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,777	07/13/2001	James Chen	600057.446C1	5768

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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04/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/905,777

Applicant(s)

CHEN, JAMES

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 25-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 11, 2008 has been entered.

Claims 1 and 2 have been amended. Claims 19-21 have been canceled. Claims 1-18 and 25-28 are pending. In order to advance prosecution, the Species Election requirement mailed 4/13/2005 is withdrawn. Claims 1-18 and 25-28 are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 2 have been amended to recite the total fluence of light used for irradiating as between 500J/cm² and 10000J/cm². Applicant points to original claim 21 and the specification at page 15, lines 8-9. It is noted that these citations recite a range between 500 joules and 10000joules and that the specification refers to this energy in term of deliver to the treatment site. Applicant has provided a reference which defines the term “fluence” in terms of energy per area. All arguments are considered but not found persuasive. While fluence would be known to one of skill in the art as energy impinging on an area, the treatment area is undefined by the originally filed disclosure and could be in terms of energy per m² or energy per

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(inches)². Therefore, the limitation between 500 joules/cm² and 10000joules/cm² is not supported by the originally filed disclosure.

Claims 1-18 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ligands which are antibodies that specifically bind to antigens specific for the targeted lesion, does not reasonably provide enablement for ligands which are part of a ligand receptor binding pair such as biotin-streptavidin, chemokine-chemokine receptor, growth factor-growth factor receptor, or ligands which are LDL, VLDL, heparin or angiotensin II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

It is well known in the art that antibodies can be used to specifically target diagnostic or therapeutic agents in vivo to specific sites via antigen-antibody interactions which are specific to the targeted tissues. However, the instant claims encompass binding pairs such as biotin-streptavidin, chemokine-chemokine receptor, growth factor-growth factor receptor, or ligands which are LDL, VLDL, heparin or angiotensin II which would not be specific for the targeting of the instant photosensitizing agents to a vascular lesion. There are no teachings in the specification or art of record which would support the use of a targeting agent to a vascular lesion which was based on the specific binding of biotin/streptavidin, a chemokine, a growth factor, LDL, VLDL, heparin or angiotensin II to vascular lesions. One of skill in the art would be subject to undue experimentation in order to practice the broadly claimed invention in the application of specific ligands other than antibodies which bind selectively to the targeted lesions.

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All other rejections and objections as set forth in the prior office action are withdrawn in light of applicants amendments and arguments.

It is noted that WO98//50034 (reference BR of the IDS filed 4/4/02) states "...it will likely be possible to use a plurality of lower power light sources and to administer the light therapy for an extended period of time" (page 3, lines 12-16). However, the reference fails to disclose or suggest the parameters of the light power, or the duration of the therapy.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643